

K063017  
Page 1 of 2**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Device Name**  
26 September 2006

DEC 27 2006

**COMPANY:** Aesculap®, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 2916714

**CONTACT:** Matthew M. Hull  
610-984-9072 (phone)  
610-791-6882 (fax)

**TRADE NAME:** SternumFix Sternal Closure System

**COMMON NAME:** Metallic Cerclage Fixation System

**CLASSIFICATION NAME:** Bone fixation cerclage

**REGULATION NUMBER:** 888.3010

**PRODUCT CODE:** JDQ

**SUBSTANTIAL EQUIVALENCE**

Aesculap®, Inc. believes that the SternumFix Sternal Closure System is substantially equivalent to:

- 1) Ethicon Stainless Steel Suture Wire (K931271/ K946173)
- 2) Aesculap CranioFix Titanium Clamp System (K040864)
- 3) Synthes Sternal Fixation System (K010943)

**DEVICE DESCRIPTION**

The Aesculap SternumFix Sternal Closure System consists of an implantable single use clamp made of titanium alloy (TiAl6V4) and a specially designed applicator instrument.

**INDICATIONS FOR USE**

The Aesculap SternumFix Sternal Closure System is intended for use in primary or secondary closure/ repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

K063017  
Page 2 of 2**TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))**

The design of the clamp and the applier are based upon the proven design features of the Aesculap CranioFix clamp and applier. The implant material (TiAl4V6) is the same as that used in the CranioFix implant. The packaging and sterilization are the same as that used for CranioFix as well. The efficacy of the SternumFix was compared to that of the current standard of care: wire cerclage fixation (Ethicon SS Suture). The indicated use for this device is similar to that of the Synthes Sternal Fixation System.

**PERFORMANCE DATA**

Mechanical testing of the SternumFix and the predicate Ethicon Stainless Steel proved the efficacy of the new device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Aesculap, Inc.  
% Mr. Matthew M. Hull  
Regulatory Affairs Manager  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

DEC 27 2006

Re: K063017  
Trade/Device Name: SternumFix Sternal Closure System  
Regulation Number: 21 CFR 888.3010  
Regulation Name: Bone fixation cerclage  
Regulatory Class: Class II  
Product Code: JDQ  
Dated: September 29, 2006  
Received: October 2, 2006

Dear Mr. Hull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson, M.S.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Page 1 of 1

**A. INDICATIONS FOR USE STATEMENT**510(k) Number: K063017

Device Name:

Indications for Use:

The Aesculap SternumFix Sternal Closure System is intended for use in primary or secondary closure/ repair of the sternum following sternotomy or fracture of the sternum to stabilize the sternum and promote fusion.

Prescription Use X and/or Over-the-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

---

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

510(k) Number K063017